DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Office of Inspector General

42 CFR Parts 409, 410, 411, 412, 413, 419, 424, 489, 498, and 1003

[HCFA-1005-FC]

RIN 0938-AI56

Medicare Program; Prospective Payment System for Hospital Outpatient Services

AGENCY: Health Care Financing Administration (HCFA), HHS, and Office of Inspector General (OIG), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period implements a prospective payment system for hospital outpatient services furnished to Medicare beneficiaries, as set forth in section 1833(t) of the Social Security Act. It also establishes requirements for provider departments and provider-based entities, and it implements section 9343(c) of the Omnibus Budget Reconciliation Act of 1986, which prohibits Medicare payment for nonphysician services furnished to a hospital outpatient by a provider or supplier other than a hospital, unless the services are furnished under an arrangement with the hospital. In addition, this

rule establishes in regulations the extension of reductions in payment for costs of hospital outpatient services required by section 4522 of the Balanced Budget Act of 1997, as amended by section 201(k) of the Balanced Budget Refinement Act of 1999.

DATES: Effective date: July 1, 2000, except that the changes to §412.24(d)(6), new §413.65, and the changes to §489.24(h), §498.2, and §498.3 are effective **[OFR--Insert 6 months after the date of publication in the Federal Register.]**.

Applicability date: For Medicare services furnished by all hospitals, including hospitals excluded from the inpatient prospective payment system, and by community mental health centers, the effective date for implementation of the hospital outpatient prospective payment system is July 1, 2000.

Comment date: Comments on the provisions of this rule resulting from the Balanced Budget Refinement Act of 1999 will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on **[OFR--Insert 60 days after the date of publication in the Federal Register]**. We will not consider comments concerning provisions that remain unchanged from the September 8, 1998

proposed rule or that were revised based on public comment. See section VIII for a more detailed discussion of the provisions subject to comment.

ADDRESSES: Mail written comments (one original and three copies) to the following address ONLY: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-1005-FC, P.O. Box 8013, Baltimore, MD 21244-8013.

If you prefer, you may deliver, by courier, your written comments (one original and three copies) to one of the following addresses:

Room 443-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201, or

C5-14-03, Central Building,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Comments mailed to those addresses may be delayed and could be considered late.

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Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (Phone (202) 690-7890).

For comments that relate to information collection requirements, mail a copy of comments to:

Health Care Financing Administration,

Office of Information Services,

Security and Standards Group,

Division of HCFA Enterprise Standards,

Room N2-14-26, 7500 Security Boulevard,

Baltimore, MD 21244-1850,

Attn: John Burke, HCFA-1005-FC; and

Lauren Oliven, HCFA Desk Officer,

Office of Information and Regulatory Affairs,

Room 3001, New Executive Office Building,

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FOR FURTHER INFORMATION CONTACT:

Janet Wellham, (410) 786-4510 or Chuck Braver, (410)786-6719 (for general information).

Joel Schaer (OIG), (202) 619-0089 (for information concerning civil money penalties).

Kitty Ahern, (410) 786-4515 (for information related to the classification of services into ambulatory payment classification (APC) groups).

George Morey (410) 786-4653 (for information related to the determination of provider-based status).

Janet Samen (410) 786-9161 (for information on the application of APCs to community mental health centers).

SUPPLEMENTARY INFORMATION:

To assist readers in referencing sections contained in this document, we are providing the following table of contents. Within each section, we summarize pertinent material from our proposed rule of September 8, 1998 (63 FR 47552) followed by public comments and our responses.

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Alphabetical List of Acronyms Appearing in the Final Rule

APC	Ambulatory payment classification
APG	Ambulatory patient group
ASC	Ambulatory surgical center
AWP	Average wholesale price
BBA 1997	Balanced Budget Act of 1997
BBRA 1999	Balanced Budget Refinement Act of 1999
CAH	Critical access hospital
CAT	Computerized axial tomography
CCI	[HCFA's] Correct Coding Initiative
CCR	Cost center specific cost-to-charge ratio
CCU	Coronary care unit

CMHC	Community mental health center
CMP	Civil money penalty
CORF	Comprehensive outpatient rehabilitation facility
CPI	Consumer Price Index
CPT	[Physicians'] Current Procedural Terminology, 4th Edition, 2000, copyrighted by the American Medical Association
DME	Durable medical equipment
DMEPOS	DME, orthotics, prosthetics, prosthetic devices, prosthetic implants and supplies
DRG	Diagnosis-related group
DSH	Disproportionate share hospital
EACH	Essential access community hospital
EBAA	Eye Bank Association of America
ED	Emergency department
EMS	Emergency medical services
EMTALA	Emergency Medical Treatment and Active Labor Act
ENT	Ear/Nose/Throat
ESRD	End-stage renal disease
FDA	Food and Drug Administration
FDO	Formula-driven overpayment
FQHC	Federally qualified health center
HCPCS	HCFA Common Procedure Coding System
HHA	Home health agency

HRSA	Health Resources and Services Administration
ICD-9-CM	International Classification of Diseases, Ninth Edition, Clinical Modification
ICU	Intensive care unit
IHS	Indian Health Service
IME	Indirect medical education
IOL	Intraocular lens
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LTH	Long-term hospital
MDH	Medicare-dependent hospital
MedPAC	Medicare Payment Advisory Commission
MRI	Magnetic resonance imaging
MSA	Metropolitan statistical area
NECMA	New England County Metropolitan Area
OBRA	Omnibus Budget Reconciliation Act
OT	Occupational therapy
PPO	Preferred provider organization
PPS	Prospective payment system
RFA	Regulatory Flexibility Act
RHC	Rural health clinic
RPCH	Rural primary care hospital
RRC	Rural referral center
SCH	Sole community hospital

SGR Sustainable growth rate

SNF Skilled nursing facility

TEFRA Tax Equity and Fiscal Responsibility Act of 1982

TPA Tissue Plasminogen Activator

Y2K Year 2000

I. Background

A. General and Legislative History

When the Medicare program was first implemented, it paid for hospital services (inpatient and outpatient) based on hospital-specific reasonable costs attributable to serving Medicare beneficiaries. Later, the law was amended to limit payment to the lesser of a hospital's reasonable costs or its customary charges. In 1983, section 601 of the Social Security Amendments of 1983 (Pub. L. 98-21) completely revised the cost-based payment system for most hospital inpatient services by enacting section 1886(d) of the Social Security Act (the Act). This section provided for a prospective payment system (PPS) for acute hospital inpatient stays, effective with hospital cost reporting periods beginning on or after October 1, 1983.

Although payment for most inpatient services became subject to the PPS, Medicare hospital outpatient services continued to be paid based on hospital-specific costs, which

provided little incentive for hospitals to furnish outpatient services efficiently. At the same time, advances in medical technology and changes in practice patterns were bringing about a shift in the site of medical care from the inpatient to the outpatient setting. During the 1980s, the Congress took steps to control the escalating costs of providing outpatient care. The Congress amended the statute to implement across-the-board reductions of 5.8 percent and 10 percent to the amounts otherwise payable by Medicare for hospital operating costs and capital costs, respectively, and enacted a number of different payment methods for specific types of hospital outpatient services. These methods included fee schedules for clinical diagnostic laboratory tests, orthotics, prosthetics, and durable medical equipment (DME); composite rate payment for dialysis for persons with end-stage renal disease (ESRD); and payments based on blends of hospital costs and the rates paid in other ambulatory settings such as separately certified ambulatory surgical centers (ASCs) or physician offices for certain surgery, radiology, and other diagnostic procedures. However, Medicare payment for services performed in the hospital outpatient setting remains largely cost-based.

In the Omnibus Budget Reconciliation Act of 1986 (OBRA 1986) (Pub. L. 99-509), the Congress paved the way for development of a PPS for hospital outpatient services. Section 9343(g) of OBRA 1986 mandated that fiscal intermediaries require hospitals to report claims for services under the HCFA Common Procedure Coding System (HCPCS). Section 9343(c) of OBRA 1986 extended the prohibition against unbundling of hospital services under section 1862(a)(14) of the Act to include outpatient services as well as inpatient services. The HCPCS coding enabled us to determine which specific procedures and services were being billed, while the extension of the prohibition against unbundling ensured that all nonphysician services provided to hospital outpatients would be billed only by the hospital, not by an outside supplier, and, therefore, would be reported on hospital bills and captured in the hospital outpatient data that could be used to develop an outpatient PPS.

A proposed rule to implement section 9343(c) was published in the **Federal Register** on August 5, 1988. However, those regulations were never published as a final rule, so we included them in the hospital outpatient PPS proposed rule published in the **Federal Register** on

September 8, 1998 (63 FR 47552) and will implement them as part of this final rule.

Section 1866(g) of the Act, as added by section 9343(c) of OBRA 1986, and amended by section 4085(i)(17) of the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987) (Pub. L. 100-203), authorizes the Department of Health and Human Services' Office of Inspector General to impose a civil money penalty (CMP), not to exceed $2,000, against any individual or entity who knowingly and willfully presents a bill in violation of an arrangement (as defined in section 1861(w)(1) of the Act).

In section 9343(f) of the OBRA 1986 and section 4151(b)(2) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508), the Congress required that we develop a proposal to replace the current hospital outpatient payment system with a PPS and submit a report to the Congress on the proposed system.

The Secretary submitted a report to the Congress on March 17, 1995, summarizing the research we conducted searching for a way to classify outpatient services for purposes of developing an outpatient PPS. The report cited ambulatory patient groups (APGs), developed by 3M-Health Information Systems (3M-HIS) under a cooperative grant with

HCFA, as the most promising classification system for grouping outpatient services and recommended that APG-like groups be used in designing a hospital outpatient PPS.

The report also presented a number of options that could be used, once a PPS was in place, for addressing the issue of rapidly growing beneficiary coinsurance. As a separate issue, we recommended that the Congress amend the provisions of the law pertaining to the blended payment methods for ASC surgery, radiology, and other diagnostic services to correct an anomaly that resulted in a less than full recognition of the amount paid by the beneficiary in calculating program payment (referred to as the formula-driven overpayment).

Three sections of the Balanced Budget Act of 1997 (the BBA 1997) (Pub. L. 105-33), enacted on August 5, 1997, affect Medicare payment for hospital outpatient services. Section 4521 of the BBA 1997 eliminates the formula-driven overpayment for ambulatory surgical center procedures, radiology services, and diagnostic procedures furnished on or after October 1, 1997. In November 1998, we issued cost report instructions (Provider Reimbursement Manual, Part II, Chapter 36, Transmittal 4) that implemented this provision for services furnished on or after October 1, 1997. Section

4522 of the BBA 1997 amends section 1861(v)(1)(S)(ii) of the Act by extending cost reductions in payment for hospital outpatient operating costs and hospital capital costs, 5.8 percent and 10 percent respectively, before January 1, 2000. Section 4523 of the BBA 1997 amends section 1833 of the Act by adding subsection (t), which provides for implementation of a PPS for outpatient services. (Under Section 4523 of the BBA 1997 the outpatient PPS does not apply to cancer hospitals before January 1, 2000.) Set forth below in section I.B is a detailed description of the changes made by the BBA 1997.

On November 29, 1999, the Balanced Budget Refinement Act of 1999 (the BBRA 1999), Pub. L. 106-113, was enacted. This Act made major changes that affect the proposed hospital outpatient PPS. The legislative changes are summarized in section I.E, below. More specific details on individual provisions that we are implementing in this final rule with comment period are included under the various sections of this preamble.

B. Summary of Provisions in the Balanced Budget Act of 1997 (the BBA 1997)

1. Prospective Payment System (PPS)

Section 4523 of the BBA 1997 amended section 1833 of the Act by adding subsection (t), which provides for a PPS for hospital outpatient department services. (The following citations reflect the statute as enacted by the BBA 1997.) Section 1833(t)(1)(B) of the Act authorizes the Secretary to designate the hospital outpatient services that would be paid under the PPS. That section also requires that the hospital outpatient PPS include hospital inpatient services designated by the Secretary that are covered under Part B for beneficiaries who are entitled to Part A benefits but who have exhausted them or otherwise are not entitled to them. Section 1833(t)(1)(B)(iii) of the Act specifically excludes ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule.

Section 1833(t)(2) of the Act sets forth certain requirements for the hospital outpatient PPS. The Secretary is required to develop a classification system for covered outpatient services that may consist of groups arranged so that the services within each group are comparable clinically and with respect to the use of resources.

Section 1833(t)(2)(C) of the Act specifies data requirements for establishing relative payment weights. The

weights are to be based on the median hospital costs determined by 1996 claims data and data from the most recent available cost reports. Section 1833(t)(2)(D) of the Act requires that the portion of the Medicare payment and the beneficiary coinsurance that are attributable to labor and labor-related costs be adjusted for geographic wage differences in a budget neutral manner.

The Secretary is authorized under section 1833(t)(2)(E) of the Act to establish, in a budget neutral manner, other adjustments, such as outlier adjustments or adjustments for certain classes of hospitals, that are necessary to ensure equitable payments. Section 1833(t)(2)(F) of the Act requires the Secretary to develop a method for controlling unnecessary increases in the volume of covered outpatient services.

Section 1833(t)(3) of the Act specifies how beneficiary deductibles are to be treated in calculating the Medicare payment and beneficiary coinsurance amounts and requires that rules be established regarding determination of coinsurance amounts for covered services that were not furnished in 1996. The statute freezes beneficiary coinsurance at 20 percent of the national median charges for covered services (or group of covered services) furnished

during 1996 and updated to 1999 using the Secretary's estimated charge growth from 1996 to 1999.

Section 1833(t)(3) of the Act also prescribes the formula for calculating the initial conversion factor used to determine Medicare payment amounts for 1999 and the method for updating the conversion factor in subsequent years.

Sections 1833(t)(4) and (t)(5) of the Act describe the method for determining the Medicare payment amount and the beneficiary coinsurance amount for services covered under the outpatient PPS. Section 1833(t)(5)(B) of the Act requires the Secretary to establish a procedure whereby hospitals may voluntarily elect to reduce beneficiary coinsurance for some or all covered services to an amount not less than 20 percent of the Medicare payment amount. Hospitals are further allowed to disseminate information on any such reductions of coinsurance amounts. Section 4451 of the BBA 1997 added section 1861(v)(1)(T) to the Act, which provides that any reduction in coinsurance must not be treated as a bad debt.

Section 1833(t)(6) authorizes periodic review and revision of the payment groups, relative payment weights, wage index, and conversion factor.

Section 1833(t)(7) of the Act describes how payment is to be made for ambulance services, which are specifically excluded from the outpatient PPS under section 1833(t)(1)(B) of the Act.

Section 1833(t)(8) of the Act provides that the Secretary may establish a separate conversion factor for services furnished by cancer hospitals that are excluded from hospital inpatient PPS.

Section 1833(t)(9) of the Act prohibits administrative or judicial review of the hospital outpatient PPS classification system, the groups, relative payment weights, wage adjustment factors, other adjustments, calculation of base amounts, periodic adjustments, and the establishment of a separate conversion factor for those cancer hospitals excluded from hospital inpatient PPS.

Section 4523(d) of the BBA 1997 made a conforming amendment to section 1833(a)(2)(B) of the Act to provide for payment under the hospital outpatient PPS for some services described in section 1832(a)(2) that are currently paid on a cost basis and furnished by providers of services, such as comprehensive outpatient rehabilitation facilities (CORFs), home health agencies (HHAs), hospices, and community mental health centers (CMHCs). This amendment provides that

partial hospitalization services furnished by CMHCs be paid under the PPS.

2. Elimination of Formula-Driven Overpayment

Before enactment of section 4521(b) of the BBA 1997, using the blended payment formulas for ASC procedures, radiology, and other diagnostic services, the ASC or physician fee schedule portion was calculated as if the beneficiary paid 20 percent of the ASC rate or physician fee schedule amount instead of the actual amount paid, which was 20 percent of the hospital's billed charges.

Section 4521(b), which amended sections 1833(i)(3)(B)(i)(II) and 1833(n)(1)(B)(i) of the Act, corrects this anomaly by changing the blended calculations so that all amounts paid by the beneficiary are subtracted from the total payment in the calculation to determine the amount due from the program. Effective for services furnished on or after October 1, 1997, payment for surgery, radiology, and other diagnostic services calculated by blended payment methods is now calculated by subtracting the full amount of coinsurance due from the beneficiary (based on 20 percent of the hospital's billed charges).

3. Extension of Cost Reductions

Section 1861(v)(1)(S)(ii) of the Act was amended by section 4522 of the BBA 1997 to require that the amounts

otherwise payable for hospital outpatient operating costs and capital costs be reduced by 5.8 percent and 10 percent, respectively, through December 31, 1999.

C. The September 8, 1998 Proposed Rule

We published a proposed rule in the **Federal Register** on September 8, 1998 (63 FR 47552) setting forth the proposed PPS for hospital outpatient services. In that proposed rule, we explained that, due to Year 2000 (Y2K) systems concerns, implementation of the new payment system would be delayed until after January 1, 1999. (The statement in the rule that the statute requires implementation "effective January 1, 1999," and other similar statements in other rules, were not intended to mean that the statute requires retroactive implementation of the hospital outpatient PPS. As noted elsewhere in this rule, the statute does not impose such a requirement.) As noted in that document, the scope of systems changes required to implement the hospital outpatient PPS is so enormous as to be impossible to accomplish concurrently with the critical work that we, our contractors, and our provider-partners had to perform to ensure that all of our respective systems were Y2K compliant. Section XI of the proposed rule (63 FR 47605) explains in greater detail the reasons for delaying implementation.

The proposed rule originally provided for a 60-day comment period. However, the comment period was extended four times, ultimately ending on July 30, 1999. (See 63 FR 63429, November 13, 1998; 64 FR 1784, January 12, 1999; 64 FR 12277, March 12, 1999; and 64 FR 36320; July 6, 1999.)

On June 30, 1999, we published a correction notice (64 FR 35258) to correct a number of technical and typographical errors contained in the September 8, 1998 proposed rule. The numerical values in the proposed rule reflected incorrect data and data programming. Among other corrections, the notice set forth revised numerical values for the current payment, total services (total units), relative weights, proposed payment rates, national unadjusted coinsurance, minimum unadjusted coinsurance, and service-mix index.

D. Overview of Public Comments

We received approximately 10,500 comments in response to our September 8, 1998 proposed rule. That count includes the numerous requests from hospital and other interested groups and organizations that we extend the public comment period to allow additional time for analysis of the impact of our proposals. As we explain above, we extended the comment period four times, to end finally on July 30, 1999.

In addition to receiving comments from a number of organizations representing the full spectrum of the hospital industry, we received comments from beneficiaries and their families, physicians, health care workers, individual hospitals, professional associations and societies, legal and nonlegal representatives and spokespersons for beneficiaries and hospitals, members of the Congress, and other interested citizens. The majority of comments addressed our proposals regarding payment for: corneal tissue; payment for high-cost technologies, both existing and future; payment for blood and blood products; and payment for high cost drugs, including chemotherapy agents. We also received numerous comments addressing: our approach to ratesetting using the ambulatory payment classification (APC) system; our method of calculating the payment conversion factor; and the potentially negative impact of the proposed hospital outpatient PPS on hospital revenues. In addition, we received many comments concerning the proposed regulations for provider-based entities.

We carefully reviewed and considered all comments received timely. The many modifications that we made to our proposed regulations in response to commenters' suggestions and recommendations are reflected in the provisions of this

final rule. Comments and our responses are addressed by topic in the sections that follow.

E. Summary of Relevant Provisions in the Balanced Budget Refinement Act of 1999 (the BBRA 1999)

As noted above, subsequent to publication of the proposed rule, the BBRA 1999 was enacted on November 29, 1999. The BBRA 1999 made major changes that affect the proposed hospital outpatient PPS. Because these changes are effective with the implementation of the PPS, we have had to make some revisions from the September 8, 1998 proposed rule. The provisions of the BBRA 1999 that we are implementing in this final rule with comment period follow.

1. Outlier Adjustment

Section 201(a) of the BBRA 1999 amends section 1833(t) by redesignating paragraphs (5) through (9) as paragraphs (7) through (11) and adding a new paragraph (5). New section 1833(t)(5) of the Act provides that the Secretary will make payment adjustments for covered services whose costs exceed a given threshold (that is, an outlier payment). This section describes how the additional payments are to be calculated and caps the projected outlier payments at no more than 2.5 percent of the total projected payments (sum of both Medicare and beneficiary payments to the hospital) made under hospital outpatient PPS for years

before 2004 and 3.0 percent of the total projected payments for 2004 and subsequent years.

2. Transitional Pass-Through for Additional Costs of Innovative Medical Devices, Drugs, and Biologicals

Section 201(b) of the BBRA 1999 adds new section 1833(t)(6) to the Act, establishing transitional pass-through payments for certain medical devices, drugs, and biologicals. This provision does the following: specifies the types of items for which additional payments must be made; describes the amount of the additional payment; limits these payments to at least 2 years but not more than 3 years; and caps the projected payment adjustments annually at 2.5 percent of the total projected payments for hospital outpatient services each year before 2004 and no more than 2.0 percent in subsequent years. Under this provision, the Secretary has the authority to reduce pro rata the amount of the additional payments if, before the beginning of a year, she estimates that these payments would otherwise exceed the caps.

3. Budget Neutrality Applied to New Adjustments

Section 201(c) of the BBRA 1999 amends section 1833(t)(2)(E) of the Act to require that the establishment of outlier and transitional pass-through

payment adjustments is to be made in a budget neutral manner.

4. Limitation on Judicial Review

Section 201(d) of the BBRA 1999 amends redesignated section 1833(t)(11) of the Act by extending the prohibition of administrative or judicial review to include the factors for determining outlier payments (that is, the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable total payment percentage), and the determination of additional payments for certain medical devices, drugs, and biologicals, the insignificant cost determination for these items, the duration of the additional payment or portion of the PPS payment amount associated with particular devices, drugs, or biologicals, and any pro rata reduction.

5. Inclusion in the Hospital Outpatient PPS of Certain Implantable Items

Section 201(e) of the BBRA 1999 amends section 1833(t)(1)(B) of the Act to include as covered outpatient services implantable prosthetics and DME and diagnostic x-ray, laboratory, and other tests associated with those implantable items.

6. Payment Weights Based on Mean Hospital Costs

Section 201(f) of the BBRA 1999 amends section 1833(t)(2)(C) of the Act, which specifies data requirements for establishing relative payment weights, to allow the Secretary the discretion to base the weights on either the median or mean hospital costs determined by data from the most recent available cost reports.

7. Limitation on Variation of Costs of Services Classified Within a Group

Section 201(g) of the BBRA 1999 amends section 1833(t)(2) of the Act to limit the variation of costs of services within each payment classification group by providing that the highest median (or mean cost, if elected by the Secretary) for an item or service within the group cannot be more than 2 times greater than the lowest median (or mean) cost for an item or service within the group. The provision allows the Secretary to make exceptions in unusual cases, such as for low volume items and services.

8. Annual Review of the Hospital Outpatient PPS Components

Section 201(h) of the BBRA 1999 amends redesignated section 1833(t)(8) of the Act to require at least annual review of the groups, relative payment weights, and the wage and other adjustments made by the Secretary to take into account changes in medical practice, the addition of new

services, new cost data, and other relevant information and factors. That section of the Act is further amended to require the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of provider representatives who will review the clinical integrity of the groups and weights and advise the Secretary accordingly. The panel may use data other than those collected or developed by the Department of HHS for the review and advisory purposes.

9. Coinsurance Not Affected by Pass-Throughs

Section 201(i) of the BBRA 1999 amends redesignated section 1833(t)(7) of the Act to provide that the beneficiary coinsurance amount will be calculated as if the outlier and transitional pass-throughs had not occurred; that is, there will be no coinsurance collected from beneficiaries for the additional payments made to hospitals by Medicare for these adjustments.

10. Extension of Cost Reductions

Section 201(k) of the BBRA 1999 amends section 1861(v)(1)(S)(ii) of the Act to extend until the first date that the hospital outpatient PPS is implemented, the 5.8 and 10 percent reductions for hospital operating and capital costs, respectively.

11. Clarification of Congressional Intent Regarding Base Amounts Used in Determining the Hospital Outpatient PPS

Section 201(l) of the BBRA 1999 provides that, "With respect to determining the amount of copayments described in paragraph (3)(A)(ii) of section 1833(t) of the Social Security Act, as added by section 4523(a) of the BBA, Congress finds that such amount should be determined without regard to such section, in a budget neutral manner with respect to aggregate payments to hospitals, and that the Secretary of Health and Human Services has the authority to determine such amount without regard to such section." Pursuant to this provision, we are calculating the aggregate PPS payment to hospitals in a budget neutral manner.

12. Transitional Corridors For Application of Outpatient PPS

Section 202 of the BBRA 1999 amends section 1833(t) of the Act by redesignating paragraphs (7) through (11) as paragraphs (8) through (12), and adding a new paragraph (7), which provides for a transitional adjustment to limit payment reductions under the hospital outpatient PPS. More specifically, for the years 2000 through 2003, a provider, including a CMHC, will receive an adjustment if its payment-to-cost ratio for outpatient services furnished during the year is less than a set percentage of its payment-to-cost

ratio for those services in its cost reporting period ending in 1996 (the base year). Two categories of hospitals, rural hospitals with 100 or fewer beds and cancer hospitals, will be held harmless under this provision. Small rural hospitals, for services furnished before January 1, 2004, will be maintained at the same payment-to-cost ratio as their base year cost report if their PPS payment-to-cost ratio is less. The hold-harmless provision applies permanently to cancer centers. Section 202 also requires the Secretary to make interim payments to affected hospitals subject to retrospective adjustments and requires that the provisions of this section do not affect beneficiary coinsurance. Finally, this provision is not subject to budget neutrality.

13. Limitation on Coinsurance for a Procedure

Section 204 of the BBRA 1999 amends redesignated section 1833(t)(8) of the Act to provide that the coinsurance amount for a procedure performed in a year cannot exceed the hospital inpatient deductible for that year.

14. Reclassification of Certain Hospitals

Section 401 of the BBRA 1999 adds section 1886(d)(8)(E) to the Act to permit reclassification of certain urban

hospitals as rural hospitals. Section 401 adds section 1833(t)(13) to the Act to provide that a hospital being treated as a rural hospital under section 1886(d)(8)(E) also be treated as a rural hospital under the hospital outpatient PPS.

II. Prohibition Against Unbundling of Hospital Outpatient Services

A. Background

Sections 9343(c)(1) and (c)(2) of OBRA 1986 amended sections 1862(a)(14) and 1866(a)(1)(H) of the Act, respectively. As revised, section 1862(a)(14) of the Act prohibits payment for nonphysician services furnished to hospital patients (inpatients and outpatients), unless the services are furnished by the hospital, either directly or under an arrangement (as defined in section 1861(w)(1) of the Act). As revised, section 1866(a)(1)(H) of the Act requires each Medicare-participating hospital to agree to furnish directly all covered nonphysician services required by its patients (inpatients and outpatients) or to have the services furnished under an arrangement (as defined in section 1861(w)(1) of the Act). Section 9338(a)(3) of OBRA 1986 affected implementation of the bundling mandate by amending section 1861(s)(2)(K) of the Act to permit services

of physician assistants to be covered and billed separately. Sections 4511(a)(2)(C) and (D) of the BBA 1997 further revised sections 1862(a)(14) and 1866(a)(1)(H) of the Act, respectively, to exclude services of nurse practitioners and clinical nurse specialists, described in section 1861(s)(2)(K)(ii) of the Act, from the bundling requirement.

B. Office of Inspector General (OIG) Civil Money Penalty Authority and Civil Money Penalties for Unbundling Hospital Outpatient Services

In order to deter the unbundling of nonphysician hospital services, section 9343(c)(3) of OBRA 1986 added section 1866(g) to the Act to provide for the imposition of civil money penalties (CMPs), not to exceed $2,000, against any person who knowingly and willfully presents, or causes to be presented, a bill or request for payment for a hospital outpatient service under Part B of Medicare that violates the requirement for billing under arrangements specified in section 1866(a)(1)(H) of the Act. In addition, section 1866(g) includes authorization to impose a CMP, in the same manner as other CMPs are imposed under section 1128A of the Act when arrangements should have been made but were not. Section 4085(i)(17) of OBRA 1987 amended section 1866(g) of the Act by deleting all references to

hospital outpatient services under Part B of Medicare. The result of this amendment is that the CMP is now applicable for services furnished to hospital patients, whether paid for under Medicare Part A or B.

In order to implement section 1866(g) of the Act, we proposed in our August 5, 1988 proposed rule that the OIG would impose a CMP against any person who knowingly and willfully presents, or causes to be presented, a bill or request for payment for a hospital outpatient service under Part B of Medicare that violates the billing arrangement under section 1866(a)(1)(H) of the Act or the requirement for an arrangement. The amount of the CMP is to be limited to $2,000 for each improper bill or request, even if the bill or request included more than one item or service.

C. Summary of Final Regulations on Bundling of Hospital Outpatient Services

In our September 8, 1998 proposed rule, we proposed to make final most of the provisions of the August 5, 1988 proposed rule but with a number of revisions that we describe in detail in the proposed rule (63 FR 47558 through 47559). We are adopting as final regulations what we proposed in the September 8, 1998 rule with the following additional changes:

- We are adding a new paragraph (b)(7) to §410.42 (Limitations on coverage of certain services furnished to hospital outpatients) to provide an exception to the hospital bundling requirements for services hospitals furnish to SNF residents as defined in §411.15(p). (Section 410.42 has been redesignated from §410.39 in the proposed rule.)

- We are making a minor change to newly redesignated paragraph (m)(2) (this language was formerly included in paragraph (m)(1)) in §411.15 (Particular services excluded from coverage) to make it clearer that the exclusion discussed in this section is referring to excluding certain services from coverage.

- Except for minor wording changes in introductory paragraph (b) of §1003.102 (Basis for civil money penalties and assessments), that section remains as it appeared in the August 5, 1988 proposed rule. Paragraph (b)(15) is redesignated from proposed paragraph (b)(4) in the August 5, 1988 proposed rule and (b)(14) in the September 8, 1998 proposed rule. Paragraphs (b)(12) through (b)(14) of §1003.102 are reserved.

- We are adding a new paragraph (k) to §1003.103 (Amount of penalty) to indicate that the OIG may impose a

penalty of not more than $2,000 for each bill or request for items and services furnished to hospital patients in violation of the bundling requirements.

! We are also amending §1003.105 (Exclusion from participation in Medicare, Medicaid and other Federal health care programs) by revising paragraph (a)(1)(i) to reflect that the basis for imposition of a CMP is also a basis for exclusion from participation in Medicare, Medicaid and other Federal health care programs.

D. Comments and Responses

Comment: One association requested that we clarify whether lab tests are subject to the bundling requirement or whether those services are included in the definition of diagnostic tests that are not required to be bundled. If lab tests are bundled, the association asked that we seek a legislative change to permit a provider, other than the lab that performs the test, to bill for the test.

Response: Laboratory tests, like all other services furnished to hospital patients, must be provided directly or under arrangements by the hospital and only the hospital may bill the program. Section 1833(h)(5)(A)(iii) of the Act provides an exception to the requirement that payment for a clinical diagnostic lab may be made only to the person or

entity that performed or supervised the performance of the test. This section provides that in the case of a clinical diagnostic laboratory test provided under arrangement made by a hospital or CAH, payment is made to the hospital.

All diagnostic tests that are furnished by a hospital, directly or under arrangements, to a registered hospital outpatient during an encounter at a hospital are subject to the bundling requirements. The hospital is not responsible for billing for the diagnostic test if a hospital patient leaves the hospital and goes elsewhere to obtain the diagnostic test.

Comment: The same association asked us to clarify that services billed to skilled nursing facilities (SNFs) under the consolidated billing requirement would be exempt from the bundling requirement for hospital outpatient services.

Response: We agree that in situations where a beneficiary receives outpatient services from a Medicare participating hospital or CAH while temporarily absent from the SNF, the beneficiary continues to be considered a SNF resident specifically with regard to the comprehensive care plan required under §483.20(b). Such services are, therefore, subject to the SNF consolidated billing provision and should be exempt from the hospital outpatient bundling

requirements. The final regulations at §410.42(b)(7) reflect this exception.

We note that the SNF consolidated billing requirements, under §411.15(p)(3)(iii), do not apply to a limited number of exceptionally intensive hospital outpatient services that lie well beyond the scope of care that SNFs would ordinarily furnish, and thus beyond the ordinary scope of SNF care plans. The hospital outpatient services that are currently included in this policy are: cardiac catheterization; computerized axial tomography (CAT) scans; MRIs; ambulatory surgery involving the use of an operating room; emergency room services; radiation therapy; angiography; and lymphatic and venous procedures. When a hospital or CAH provides these services to a beneficiary, the beneficiary's status as a SNF resident ends, but only with respect to these services. The beneficiary is now considered to be a hospital outpatient and the services are subject to hospital outpatient bundling requirements. In November 1998, we issued Program Memorandum transmittal number A-98-37, which provides additional clarification on this exclusion as well as a list of specific HCPCS codes that identify the services that are excluded from SNF consolidated billing but subject to hospital outpatient bundling.

Comment: One commenter understood that the proposed rule would permit payment for all diagnostic tests that are furnished by a hospital or other entity if the patient leaves the hospital and obtains the service elsewhere; however, the commenter requested clarification as to the treatment of "outsourced" hospital departments. The commenter stated that hospitals are increasingly outsourcing departments to providers that can furnish services efficiently. Often these providers do not operate as "under arrangements" providers to the hospital, but as free-standing providers offering outpatient services on hospital grounds. The commenter specifically asked whether a free-standing entity providing outpatient services on hospital grounds, but operated independently of the hospital is able to bill separately for services furnished or is the entity considered to be part of the hospital and required to furnish services "under arrangement."

Response: A free-standing entity, that is, one that is not provider-based, may bill for services furnished to beneficiaries who do not meet the definition of a hospital outpatient at the time the service is furnished. Our bundling requirements apply to services furnished to a

"hospital outpatient," as defined in §410.2, during an "encounter," also defined in §410.2.

Comment: One commenter indicated that while the proposed revision to §1003.102(b) accurately reflected the statutory directive that the basis for imposing a CMP is a "bill or request for payment," the proposed amendment to §1003.103(a) regarding the appropriate penalty amount to be imposed for bundling violations was in error. The commenter indicated that the OIG lacks the authority to impose a CMP in the amount of $10,000 for these violations, and that such a penalty should be not more than $2,000 for each violation.

Response: The commenter is correct. While section 231(c) of the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, increased the CMP maximum amount from $2,000 to $10,000, the statute sets forth "items or services" as the basis upon which a higher CMP amount may be assessed. However, with regard to bundling violations, the Secretary may impose a CMP only on the basis of a "bill or request for payment" rather than "for each item and service" as stated in the proposed revision to §1003.103. We are correcting this error by adding a new §1003.103(k) to indicate that the OIG may

impose a penalty of not more than $2,000 for each bill or request for items and services furnished to hospital patients in violation of the bundling requirements.